

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Frank A. Skraly and Oliver P. Peoples

Serial No.: Continuation of 09/488,348      Art Unit: Not Yet Assigned

Filed: June 20, 2003      Examiner: Not Yet Assigned

For: ***POLYHYDROXYALKANOATE BIOPOLYMER COMPOSITIONS***

Assistant Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including four (4) pages of Form PTO-1449. All of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/488,348, filed January 20, 2000, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S.S.N.: Continuation of 09/488,348  
Filed: June 20, 2003  
INFORMATION DISCLOSURE STATEMENT

### U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
3,275,610	09-27-1966	Coty	260/80
4,477,654	10-16-1984	Holmes, et al.	528/361
5,534,432	07-09-1996	Peoples, et al.	435/240.4
5,798,235	08-25-1998	Peoples, et al.	435/135

### Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
WO 99/14313	03-25-1999	Metabolix, Inc.	PCT

### Publications

BRAUNEGG, et al., "Polyhydroxyalkanoates, biopolymers from renewable resources: physiological and engineering aspects," *Journal of Biotechnology* 65:127-161 (1998).

CAO, et al., "Thermal and morphological study of fractionated poly(3-hydroxybutyric acid-co-3-hydroxypropionic acid)," *Macromol. Chem. Phys.* 198:3539-3557 (1997).

CHOI & LEE, "Factors affecting the economics of polyhydroxyalkanoate production by bacterial fermentation," *Appl. Microbiol. Biotechnol.* 51:13-21 (1999).

DOI, "Microbial Synthesis, Physical Properties, and Biodegradability of Polyhydroxyalkanoates," *Macromol. Symp.* 98:585-599 (1995).

FUKUI, et al., "Purification and characterization of NADP-linked acetoacetyl-CoA reductase from *Zoogloea ramigera* I-16-M," *Biochimica Et Biophysica Acta* 917:365-371 (1987).

GERNGROSS, et al., "Overexpression and purification of the soluble polyhydroxyalkanoate synthase from *Alcaligenes eutrophus*: Evidence for a required posttranslational modification for catalytic activity," *Biochemistry* 33:9311-9320 (1994).

HEIN, et al., "Biosynthesis of poly(4-hydroxybutyric acid) by recombinant strains of *Escherichia coli*," *FEMS Microbiol. Lett.* 153:411-418 (1997).

HII & COURTRIGHT, "Induction of acyl coenzyme A synthetase and hydroxyacyl coenzyme A dehydrogenase during fatty acid degradation in *Neurospora crassa*," *J. Bacteriol.* 150(2):981-983 (1982).

U.S.S.N.: Continuation of 09/488,348  
Filed: June 20, 2003  
INFORMATION DISCLOSURE STATEMENT

HOFMEISTER & BUCKEL, "(R)-lactyl-CoA dehydratase from Clostridium propionicum. Stereochemistry of the dehydration of (R)-2-hydroxybutyryl-CoA to crotonyl-CoA," *Eur. J. Biochem.* 206(2):547-552 (1992).

JESUDASON & MARCHESSAULT, "Synthetic Poly[(R,S)-.beta.-hydroxyalkanoates] with Butyl and Hexyl Side Chains," *Macromolecules* 27:2595-602 (1994).

LEE, et al. *Appl. Microbiol. Biotechnol.* 42(6): 901-909 (1995).

LEE, et al., "Copolymerization of gamma-valerolactone and beta-butyrolactone," *Eur. Polym. J.* 34: 117-122 (1998).

MADISON & HUISMAN, "Metabolic engineering of poly(3-hydroxyalkanoates): from DNA to plastic," *Microbiology and Molecular Biology Reviews* 63:21-53 (1999).

NAWRATH, et al., "Targeting of the polyhydroxybutyrate biosynthetic pathway to the plastids of *Arabidopsis thaliana* results in high levels of polymer accumulation," *Proc. Natl. Acad. Sci. USA* 91:12760-64 (1994).

PEOPLES & SINSKEY, "Poly- $\beta$ -hydroxybutyrate (PHB) biosynthesis in *Alcaligenes eutrophus* H16. Identification and characterization of the PHB polymerase gene (phbC)," *J. Biol. Chem.* 264:15298-15303 (1989).

PEOPLES, et al., "Biosynthetic Thiolase from *Zoogloea ramigera*," *J. Biol. Chem.* 262:97-102 (1987).

SAITO, et al., "An NADP-linked Acetoacetyl CoA reductase from *Zoogloea ramigera*," *Arch. Microbiol.* 114:211-217 (1977).

SAITO, et al., "Microbial synthesis and properties of poly(3-hydroxybutyrate-co-4-hydroxybutyrate)," *Polym. Int.* 39:169-174 (1996).

SAITO, et al., *Intl. J. Biol. Macromol.* 16(2): 99-104 (1994).

SENIOR & DAWES, "The regulation of Poly-.beta.-hydroxybutyrate Metabolism in *Azobacter beijerinckii*," *Biochem. J.* 134:225-228 (1973).

SHIMAMURA, et al., "Microbial Synthesis and Characterization of Poly(3-hydroxybutyrate-co-3-hydroxypropionate)," *Macromolecules* 27:4429-4435 (1994).

SÖHLING & GOTTSCHALK, "Molecular analysis of the anaerobic succinate degradation pathway in *Clostridium kluyveri*," *J. Bacteriol.* 178:871-880 (1996).

STEINBÜCHEL & GORENFLO, "Biosynthetic and biodegradable polyesters from renewable resources: current state and prospects," *Macromol. Symp.* 123:61-66 (1997).

U.S.S.N.: Continuation of 09/488,348  
Filed: June 20, 2003  
INFORMATION DISCLOSURE STATEMENT

STEINBÜCHEL & VALENTIN, "Diversity of bacterial polyhydroxyalkanoic acids," FEMS Microbiol. Lett. 128:219-28 (1995).

VALENTIN & DENNIS, "Production of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in recombinant *Escherichia coli* grown on glucose," J. Biotechnol. 58:33-38 (1997).

VALENTIN, et al., "Identification of 4-hydroxyhexanoic acid as a new constituent of biosynthetic polyhydroxyalkanoic acids from bacteria," Appl. Microbiol. Biotechnol. 40:710-16 (1994).

VALENTIN, et al., "Identification of 4-hydroxyvaleric acid as a constituent of biosynthetic polyhydroxyalkanoic acids from bacteria," Appl. Microbiol. Biotechnol. 36:507-14 (1992).

WILLADSEN & BUCKEL, "Assay of 4-hydroxybutyryl-CoA dehydrates from *Clostridium aminobutyricum*," FEMS Microbiol. Lett. 70:187-192 (1990).

WILLIAMS & PEOPLES, "Biodegradable plastics from plants," Chemtech 26:38-44 (1996).

YIM, et al., "Synthesis of Poly-(3-hydroxybutyrate-co-3-hydroxyvalerate) by recombinant *Escherichia coli*," Biotech. Bioengineering 49:495-503 (1996).

U.S.S.N.: Continuation of 09/488,348  
Filed: June 20, 2003  
INFORMATION DISCLOSURE STATEMENT

**Remarks**

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

*Rivka D. Monheit*  
Rivka D. Monheit  
Reg. No. 48,731

Dated: June 20, 2003

HOLLAND & KNIGHT LLP  
One Atlantic Center  
1201 West Peachtree Street, N.E.  
Suite 2000  
Atlanta, Georgia 30309-3400  
404-817-8514  
FAX 404-817-8588  
[www.hklaw.com](http://www.hklaw.com)

ATL1 #582017 v1

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Application Number	Continuation of 09/488,348
		Filing Date	June 20, 2003
		First Named Inventor	Frank A. Skraly
		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	MBX 027 DIV CON
Sheet	1	of	4

## **U.S. PATENT DOCUMENTS**

## FOREIGN PATENT DOCUMENTS

Examine  
Signature \_\_\_\_\_ Date Considered \_\_\_\_\_

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	Continuation of 09/488,348
Filing Date	June 20, 2003				
First Named Inventor	Frank A. Skraly				
Group Art Unit					
Examiner Name					
Sheet 2 of 4	Attorney Docket Number	MBX 027 DIV CON			

**OTHER ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		BRAUNEGG, et al., "Polyhydroxyalkanoates, biopolymers from renewable resources: physiological and engineering aspects," Journal of Biotechnology 65:127-161 (1998).	
		CAO, et al., "Thermal and morphological study of fractionated poly(3-hydroxybutyric acid-co-3-hydroxypropionic acid," Macromol. Chem. Phys. 198:3539-3557 (1997).	
		CHOI & LEE, "Factors affecting the economics of polyhydroxyalkanoate production by bacterial fermentation," Appl. Microbiol. Biotechnol. 51:13-21 (1999).	
		DOI, "Microbial Synthesis, Physical Properties, and Biodegradability of Polyhydroxyalkanoates," Macromol. Symp. 98:585-599 (1995).	
		FUKUI, et al., "Purification and characterization of NADP-linked acetoacetyl-CoA reductase from Zoogloea ramigera I-16-M," Biochimica Et Biophysica Acta 917:365-371 (1987).	
		GERNGROSS, et al., "Overexpression and purification of the soluble polyhydroxyalkanoate synthase from Alcaligenes eutrophus: Evidence for a required posttranslational modification for catalytic activity," Biochemistry 33:9311-9320 (1994).	
		HEIN, et al., "Biosynthesis of poly(4-hydroxybutyric acid) by recombinant strains of Escherichia coli," FEMS Microbiol. Lett. 153:411-418 (1997).	
		HILL & COURTRIGHT, "Induction of acyl coenzyme A synthetase and hydroxyacyl coenzyme A dehydrogenase during fatty acid degradation in Neurospora crassa," J. Bacteriol. 150(2):981-983 (1982).	
		HOFMEISTER & BUCKEL, "(R)-lactyl-CoA dehydratase from Clostridium propionicum. Stereochemistry of the dehydration of (R)-2-hydroxybutyryl-CoA to crotonyl-CoA," Eur. J. Biochem. 206(2):547-552 (1992).	
		JESUDASON & MARCHESSAULT, "Synthetic Poly[(R,S)-beta-hydroxyalkanoates] with Butyl and Hexyl Side Chains," Macromolecules 27:2595-602 (1994).	

Examiner's Signature	Date Considered
----------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

Complete if Known

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Application Number	Continuation of 09/488,348
Filing Date	June 20, 2003
First Named Inventor	Frank A. Skraly
Group Art Unit	
Examiner Name	

Sheet 3 of 4 Attorney Docket Number MBX 027 DIV CON

**OTHER ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		LEE, et al. Appl. Microbiol. Biotechnol. 42(6): 901-909 (1995).	
		LEE, et al., "Copolymerization of gamma-valerolactone and beta-butyrolactone," Eur. Polym. J. 34: 117-122 (1998).	
		MADISON & HUISMAN, "Metabolic engineering of poly(3-hydroxyalkanoates): from DNA to plastic," Microbiology and Molecular Biology Reviews 63:21-53 (1999).	
		NAWRATH, et al., "Targeting of the polyhydroxybutyrate biosynthetic pathway to the plastids of <i>Arabidopsis thaliana</i> results in high levels of polymer accumulation," Proc. Natl. Acad. Sci. USA 91:12760-64 (1994).	
		PEOPLES & SINSKEY, "Poly- $\beta$ -hydroxybutyrate (PHB) biosynthesis in <i>Alcaligenes eutrophus</i> H16. Identification and characterization of the PHB polymerase gene (phbC)," J. Biol. Chem. 264:15298-15303 (1989).	
		PEOPLES, et al., "Biosynthetic Thiolase from <i>Zoogloea ramigera</i> ," J. Biol. Chem. 262:97-102 (1987).	
		SAITO, et al., "An NADP-linked Acetoacetyl CoA reductase from <i>Zoogloea ramigera</i> ," Arch. Microbiol. 114:211-217 (1977).	
		SAITO, et al., "Microbial synthesis and properties of poly(3-hydroxybutyrate-co-4-hydroxybutyrate)," Polym. Int. 39:169-174 (1996).	
		SAITO, et al., Int'l. J. Biol. Macromol. 16(2): 99-104 (1994).	
		SENIOR & DAWES, "The regulation of Poly- $\beta$ -hydroxybutyrate Metabolism in <i>Azobacter beijerinckii</i> ," Biochem. J. 134:225-228 (1973).	

Examiner's Signature	Date Considered
----------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	Continuation of 09/488,348
Filing Date	June 20, 2003				
First Named Inventor	Frank A. Skraly				
Group Art Unit					
Examiner Name					
Sheet 4 of 4	Attorney Docket Number	MBX 027 DIV CON			

**OTHER ART - NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		SHIMAMURA, et al., "Microbial Synthesis and Characterization of Poly(3-hydroxybutyrate-co-3-hydroxypropionate)," Macromolecules 27:4429-4435 (1994).	
		SÖHLING & GOTTSCHALK, "Molecular analysis of the anaerobic succinate degradation pathway in Clostridium kluyveri," J. Bacteriol. 178:871-880 (1996).	
		STEINBÜCHEL & GORENFLO, "Biosynthetic and biodegradable polyesters from renewable resources: current state and prospects," Macromol. Symp. 123:61-66 (1997).	
		STEINBÜCHEL & VALENTIN, "Diversity of bacterial polyhydroxyalkanoic acids," FEMS Microbiol. Lett. 128:219-28 (1995).	
		VALENTIN & DENNIS, "Production of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in recombinant Escherichia coli grown on glucose," J. Biotechnol. 58:33-38 (1997).	
		VALENTIN, et al., "Identification of 4-hydroxyhexanoic acid as a new constituent of biosynthetic polyhydroxyalkanoic acids from bacteria," Appl. Microbiol. Biotechnol. 40:710-16 (1994).	
		VALENTIN, et al., "Identification of 4-hydroxyvaleric acid as a constituent of biosynthetic polyhydroxyalkanoic acids from bacteria," Appl. Microbiol. Biotechnol. 36:507-14 (1992).	
		WILLADSEN & BUCKEL, "Assay of 4-hydroxybutyryl-CoA dehydrates from Clostridium aminobutyricum," FEMS Microbiol. Lett. 70:187-192 (1990).	
		WILLIAMS & PEOPLES, "Biodegradable plastics from plants," Chemtech 26:38-44 (1996).	
		YIM, et al., "Synthesis of Poly-(3-hydroxybutyrate-co-3-hydroxyvalerate) by recombinant Escherichia coli," Biotech. Bioengineering 49:495-503 (1996).	

Examiner's Signature	Date Considered
----------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.